**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF OHIO,**
**EASTERN DIVISION**

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| FREDERICK ARTERS,<br><br>Plaintiff,<br><br>v.<br><br>SANDOZ INC., FORMERLY KNOWN AS GENEVA PHARMACEUTICALS, INC.,<br><br>AND<br><br>EON LABS, INC., FORMERLY KNOWN AS EON LABS MANUFACTURING, INC.<br><br>Defendants. | ) | Judge James L. Graham<br>Magistrate Elizabeth Preston Deavers<br><br>**Case No.: 2:10-cv-00142** |

**MOTION FOR JUDGMENT ON THE PLEADINGS OF DEFENDANTS SANDOZ INC. AND EON LABS, INC.**

Defendants Sandoz Inc. ("Sandoz") and Eon Labs, Inc. ("Eon") (collectively "Defendants") respectfully Move to Dismiss Plaintiff's Complaint pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. This motion is supported by the accompanying memorandum in support attached hereto.

Respectfully submitted,

*s/ David W. Walulik*

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| FREDERICK ARTERS,<br><br>Plaintiff,<br><br>v.<br><br>SANDOZ INC., FORMERLY KNOWN AS GENEVA PHARMACEUTICALS, INC.,<br><br>AND<br><br>EON LABS, INC., FORMERLY KNOWN AS EON LABS MANUFACTURING, INC.<br><br>Defendants. | ) | Judge James L. Graham<br>Magistrate Elizabeth Preston Deavers<br><br>**Case No.: 2:10-cv-00142** |

**MEMORANDUM OF LAW IN SUPPORT**
**OF MOTION FOR JUDGMENT ON THE PLEADINGS OF**
**DEFENDANTS SANDOZ INC. AND EON LABS, INC.**

Defendants Sandoz Inc. ("Sandoz") and Eon Labs, Inc. ("Eon") (collectively "Defendants") respectfully submit this Memorandum of Law in support of their Motion to Dismiss Plaintiff's Complaint (the "Complaint" or "Compl.") pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. Defendants are entitled to judgment on the pleadings because Plaintiff's claims are preempted by federal law as interpreted by the United States Supreme Court in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and the U.S. Court of Appeals for the Sixth Circuit in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011). In support of this Motion, Defendants state as follows:

## INTRODUCTION AND SUMMARY

Plaintiff Frederick Arters ("Plaintiff") brought this products liability suit in connection with Mr. Arters' ingestion of the FDA-approved prescription medication amiodarone, which Eon

manufactured and sold under the Eon name.[1] He alleges amiodarone was not safe and effective for the treatment of his atrial fibrillation and caused serious injuries, including blindness. (Compl. ¶¶ 4-5.) Plaintiff has asserted claims for negligence, violation of the Ohio Products Liability Act, R.C. 2307.71-2307.80, breach of implied warranties, and fraud, all premised on Eon's alleged failure to warn of the risks of generic amiodarone. (Compl. ¶¶ 95-191.)[2]

The drug dispensed to Mr. Arters was a "generic" pharmaceutical product manufactured under the authority and direction of the federal Food and Drug Administration ("FDA"). (Compl. ¶¶ 38-39, 47.) As a manufacturer of generic amiodarone, Eon was required by federal law to provide product labeling that was identical in all material respects to the FDA-approved labeling of the equivalent brand name drug. *See Mensing*, 131 S. Ct. at 2574. It was therefore impossible under FDA's comprehensive federal regulatory scheme for Eon to provide different or allegedly better warnings Plaintiff alleges are required by state law.[3] Because it was impossible for Eon to meet both mandatory federal labeling requirements and conflicting alleged state requirements, Plaintiff's claims are preempted by federal law and should be dismissed pursuant to the Supreme Court's recent ruling in *Mensing*.

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[1] Eon is a wholly-owned subsidiary of Sandoz. While Sandoz did not manufacture or sell the amiodarone allegedly ingested by Plaintiff nor does Plaintiff allege that Sandoz made or sold amiodarone or was negligent or committed any wrongdoing, Sandoz joins the instant Motion.

[2] Mr. Arters' wife, Barbara Arters, was formerly a plaintiff in this action. Her loss of consortium claims were dismissed by the Court on statute of limitations grounds, leaving Mr. Arters as the sole plaintiff. *See* Order Granting Mot. for Summ. J., Mar. 22, 2012, Dkt. 65.

[3] Mr. Arters lived in Virginia at the time of his injury and during his post-injury medical treatment. Because his prescription, purchase, and ingestion of amiodarone occurred in Virginia, as did his alleged injury and post-injury medical treatment, Eon believes Virginia law should apply to this action. For the purposes of this motion, however, the choice of state law is immaterial. Any state failure-to-warn law that is inconsistent with federally-mandated labeling requirements is preempted.

Plaintiff's claims are all preempted in that they, at their root, attack the sufficiency of the warnings provided by Eon. Each cause of action in the Complaint is directly dependent upon the allegation that Eon should have provided more or different information about the risks of amiodarone than was contained in Eon's federally-mandated product labeling. As the Sixth Circuit Court of Appeals, a court in this District, and numerous district courts around the country have since recognized, claims just like those pled in the Complaint alleging various causes of action attacking a generic drug's warnings and design are preempted under *Mensing*, because generic drugs are required by federal law to have the same warnings and design as the Reference Listed Drug ("RLD"). Accordingly, all of the claims asserted by Plaintiff are preempted by federal law and Defendants are entitled to judgment on the pleadings as a matter of law.

## STATEMENT OF RELEVANT FACTS

## I. REGULATORY BACKGROUND OF AMIODARONE

### A. The Federal Regulatory Scheme for Generic Drugs.

The FDA regulates the labeling of both brand name and generic drugs. *See* 21 C.F.R. § 314.50(c)(2)(i) (brand name); 21 C.F.R. § 314.94(a)(8) (generic). A manufacturer seeking FDA approval to market a new drug must first prove it is safe and effective and that the proposed label is accurate and adequate, through the filing of a New Drug Application or "NDA." *Mensing*, 131 S. Ct. at 2574. This approval process for brand-name drugs involves costly and lengthy clinical testing. *Id.*

Generic drugs are those drugs "designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety and efficacy." *Mensing*, 131 S. Ct. 2567, at 2574 n.2. Manufacturers of generic drugs must obtain prior FDA approval to manufacture and sell those drugs under the regulatory scheme set forth in what are commonly known as the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C.

§ 355(j)(2)(A). *Id.* at 2574. The Hatch-Waxman Amendments changed the approval requirements for generic drugs to require manufacturers to submit an Abbreviated New Drug Application ("ANDA") showing that the proposed generic product is identical in all material respects to a previously-approved brand name product. *See* 21 U.S.C. § 355(j)(2)(A). In order to obtain ANDA approval, a manufacturer must demonstrate the "labeling proposed . . . is the same as the labeling approved for the [brand name] drug." *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. §355(j)(2)(A)(v)). While certain minor variations between generic and brand labeling are permitted for matters like manufacturer name, expiration dates and product colors, the regulations pointedly do not permit any divergence in product warning information. *Id.*

Upon receiving the FDA's approval of an ANDA, the only duty incumbent upon a generic manufacturer under federal law with respect to its warnings is an ongoing duty of "sameness"—to ensure its generic drug's labeling remains identical to that of the RLD to which it is required to remain equivalent. *Mensing*, 131 S. Ct. at 2574-75. Generic manufacturers are expressly prohibited from independently changing their labeling in any respect without prior FDA approval. *Id.* at 2577 ("Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels."); *see also* 21 C.F.R. § 314.150(b)(10) (authorizing the FDA to revoke the approval of a generic drug if its labeling "is no longer consistent with that for the listed drug"). For a generic manufacturer to independently change the warning labeling, even to strengthen it, would be a violation of federal law. *Id.* at 2570. Thus, generic manufacturers like Defendants have no mechanism through which they may independently alter or strengthen their labeling, as Plaintiff alleges Eon should have done.

**B. Eon's Amiodarone.**

In order to manufacture generic amiodarone, Eon was required to and did submit an ANDA for the product to the FDA. *See* 21 U.S.C. § 355(j)(2)(A). The FDA approved Eon's ANDA for amiodarone on December 23, 1998. (Compl. ¶ 95.)[4] FDA's approval of Eon's ANDA included approval of the proposed labeling, which was determined by the FDA to contain warnings identical in all material respects to those for the equivalent brand name drug. After Eon's amiodarone ANDA was approved by the FDA, Eon was required at all times by federal law to keep its amiodarone labeling and design consistent with the approved labeling and design for the equivalent RLD, Cordarone®. *See Mensing*, 131 S. Ct. at 2575-77. Thus, taking Plaintiff's allegations in the Complaint as true for purposes of this Motion for Judgment on the Pleadings, the amiodarone allegedly manufactured by Eon and ingested by Plaintiff is a generic pharmaceutical product required by the FDA to be labeled at all times with the same FDA-approved warnings for the brand name equivalent drug, Cordarone®.

[4] This information may be viewed at the FDA's National Drug Code directory. FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails (last viewed on 8/8/2012). The contents of the FDA website are public records upon which the Court is entitled to rely for purposes of this Motion for Judgment on the Pleadings. *See, e.g.*, *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 999 (9th Cir. 2010) (noting courts deciding a motion to dismiss may take judicial notice of government website documents, including drug labels on the FDA website); *Lum v. Bank of Am.*, 361 F.3d 217, 221 n.3 (3d Cir. 2004); *Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 (3d Cir. 2004) (taking judicial notice of contents of U.S. Patent and Trademark Office website); *Fellner v. Tri-Union Seafoods, L.L.C.*, Civ. A. No. 06-cv-0688, 2010 WL 1490927, at *6 n.8 (D.N.J. Apr. 13, 2010) (taking judicial notice of FDA records when considering motion to dismiss); *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 367 (E.D.N.Y. 2010) (same); *In re Amgen Secs. Litig.*, 544 F. Supp. 2d 1009, 1023 (C.D. Cal. 2008) (taking judicial notice of drug labels on FDA website as documents "not subject to reasonable dispute"); *see also* Fed. R. Evid. 201.

## II. PLAINTIFF'S CLAIMS

Plaintiff alleges he consumed Eon's amiodarone from November 2003 to February 2004, and thereafter suffered eye damage and vision loss.[5] (Compl. ¶¶ 1-5.) Plaintiff has asserted claims for negligence, violation of the Ohio Products Liability Act, breach of implied warranties, and fraud. For each of these claims, Plaintiff seeks to hold Defendants liable for the purportedly misleading or inadequate warnings provided with Eon's amiodarone product, or for a purported failure to provide additional warnings.

Specifically, Plaintiff contends that "[w]hen Eon placed its Amiodarone in the stream of commerce, Amiodarone was not accompanied by any meaningful warnings regarding the significant risk of medical conditions, including . . . eye damage." (*Id.* ¶ 150.) Plaintiff's claims all necessarily attack the sufficiency of the FDA-mandated warnings provided by Eon with its amiodarone. In essence, Plaintiff's Complaint asserts that Eon was negligent for following federal law regarding mandatory labeling. These are exactly the sort of claims that *Mensing* held are preempted by federal law.

## ARGUMENT

## I. STANDARD OF REVIEW

Courts apply the same analysis to motions for judgment on the pleadings under Rule 12(c) as they apply to motions to dismiss under Fed. R. Civ. P. 12(b)(6). *McGath v. Hamilton Local Sch. Dist.*, No. 2:10-CV-1156, 2012 WL 262336, at *3 (S.D. Ohio Jan. 30, 2012) (citing *Warrior Sports, Inc. v. Nat'l Collegiate Athletic Ass'n*, 623 F.3d 281, 284 (6th Cir. 2010)). The difference between Rule 12(c) and Rule 12(b)(6) motions is that, "on a motion for judgment on the pleadings, the Court reviews not only the complaint, but also the answer and any written

[5] This section of the Statement of Relevant Facts is based upon the allegations in the Complaint, which for purposes of Defendants' Rule 12(c) Motion only, are assumed to be true.

instruments attached thereto." *Sanders v. PFG Mortg. Trust I*, 11-CV-13884, 2012 WL 666799, at *2 (E.D. Mich. Feb. 29, 2012); *see also Weiner v. Klais & Co.*, 108 F.3d 86, 88 (6th Cir. 1997). A motion for judgment on the pleadings is appropriately granted when the movant establishes that there is no material issue of fact to be resolved and that he is entitled to judgment as a matter of law. *Tucker v. Middleburg–Legacy Place*, 539 F.3d 545, 549 (6th Cir. 2008).

To survive a motion for judgment on the pleadings under Rule 12(c), "a complaint must contain direct or inferential allegations respecting all the material elements under some viable legal theory." *Commercial Money Ctr., Inc. v. Ill. Union Ins. Co.*, 508 F.3d 327, 336 (6th Cir. 2007). Plaintiff's factual allegations "need to be sufficient to give notice to the defendant as to what claims are alleged, and the plaintiff must plead 'sufficient factual matter' to render the legal claim plausible, i.e., more than merely possible." *Fritz v. Charter Twp. of Comstock*, 592 F.3d 718, 722 (6th Cir. 2010) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 677-79 (2009)). Plaintiff's factual allegations must "possess enough heft" to present a plausible entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). "A 'legal conclusion couched as a factual allegation' need not be accepted as true, nor are recitations of the elements of a cause of action sufficient" to withstand a motion for judgment on the pleadings. *McGath*, 2012 WL 262236, at *3 (citing *Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009)).

## II. PLAINTIFF'S CLAIMS ARE PREEMPTED BY FEDERAL LAW

### A. Preemption Is a Pure Question of Law.

Federal preemption is a pure question of law that may be determined by this Court on the face of the pleadings. *See, e.g., Fulgenzi v. Pliva, Inc.*, No. 5:09-CV-1767, 2012 WL 1110009 (N.D. Ohio Mar. 31, 2012) (granting generic drug manufacturer's motion to dismiss based on *Mensing* preemption); *Phelps v. Wyeth, Inc.*, Civ. No. 6:09-cv-06168-TC, 2012 WL 1499343, at *6 (D. Or. Apr. 24, 2012) ("when federal law preempts all claims in a complaint, dismissal for

failure to state a claim is appropriate"). Thus, the applicability of *Mensing* preemption to Plaintiff's claims may be determined in a Motion for Judgment on the Pleadings, and any attempt by Plaintiff to argue for discovery on this issue is inapposite and should be rejected. *See, e.g.*, *Brinkley v. Pfizer, Inc.*, No. 10-0274-CV-W-SOW, 2012 WL 1564945, at *1-6 (W.D. Mo. Apr. 12, 2012) (granting motion for judgment on the pleadings on the basis of preemption under *Mensing*); *Bowman v. Wyeth LLC*, No. 10-1946, 2012 WL 684116, at *1-7 (D. Minn. Mar. 2, 2012) (same). Furthermore, because all of Plaintiff's claims are preempted and must fail as a matter of law—as fully demonstrated below—Plaintiff should not be allowed to amend his Complaint, as amendment would be futile. *See Henderson*, 809 F.Supp.2d at 1376-81 (denying leave to amend complaint in case involving Phenytoin and similar alleged injuries because amendment would be futile and claims were preempted); *Fulgenzi*, 2012 WL 1110009, at *7 ("even if pleading deficiencies could be remedied, dismissal of these claims is still appropriate").

**B. *Mensing* and Its Progeny Mandate Preemption of Plaintiff's Claims.**

Article VI of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. It is axiomatic that whenever state law and federal law are in conflict, federal law must prevail. *See, e.g., Hillsborough Cnty., Fla. v. Automated Med. Labs, Inc.*, 471 U.S. 707, 713 (1985) ("[S]tate law is nullified to the extent that it actually conflicts with federal law."); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (State law is preempted where it "penalizes what federal law requires."). State law also is preempted where "compliance with both federal and state regulations is a physical impossibility." *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). This

impossibility of compliance with both state and federal law in generic drug product labeling is exactly what the Court found to exist in *Mensing*. 131 S. Ct. at 2593.

In *Mensing*, the Supreme Court found all state tort claims premised upon a purported failure to warn of the risks associated with generic pharmaceutical products to be preempted by federal law. Because generic manufacturers like Defendants are prohibited from changing their labeling, even to strengthen their warnings, it would be impossible for Eon to comply both with state failure-to-warn claims (that allegedly would have required stronger warnings) and federal law (which prohibit any variance from the brand name manufacturer's labeling). As such, state law failure-to-warn claims attacking the sufficiency of a generic drug's labeling are preempted. *Id*. at 2578.

Since *Mensing* was decided, courts addressing this issue, including the Sixth Circuit and district courts within this Circuit, have consistently dismissed on preemption grounds claims identical those made in this case. Most notably, the Sixth Circuit's binding post-*Mensing* opinion in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011 ), *cert. denied,* 132 S. Ct. 2103 (2012), inescapably compels the conclusion that all of Plaintiff's claims are preempted by federal law. *Smith* involved three companion cases in which the United States District Court for the Western District of Kentucky dismissed the plaintiffs' lawsuits against the generic drug defendants as preempted, "finding a conflict between their tort claims and the federal regulation of generic drugs." *Smith*, 657 F.3d at 42. In supplemental briefing filed after *Mensing* was announced, the *Smith* plaintiffs argued that "[w]hile the *Mensing* decision alters the theories of liability that [plaintiffs] can pursue, viable causes of action remain against [the generic drug defendants]," including claims for negligence, breach of warranty, and design defect. *See*

Plaintiffs' Supplemental Brief, *Smith v. Wyeth, Inc.*, No. 09-5460, 2011 WL 3662688, at *1 (6th Cir. Sept. 22, 2011).

Rejecting the plaintiffs' argument that any of their claims survived *Mensing*, the Sixth Circuit held:

> [T]he plaintiffs contend that the district court erred in concluding that their state-law failure-to-warn claims against the generic defendants were preempted by federal law. Their arguments must fail, however, given the recent decision of the Supreme Court in [*Mensing*]. Just as in the present case, the plaintiffs in *Mensing* alleged that their long-term use of generic metoclopramide caused tardive dyskinesia, and they predicated the manufacturers' liability under state law on the failure to provide adequate warnings on the product's label. The Supreme Court held unequivocally, however, that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims. The plain language of the [*Mensing*] decision compels the same result here.

*Smith*, 657 F.3d at 423.

Because Plaintiff's Complaint raises claims that are legally indistinguishable from the claims asserted in *Mensing* and *Smith*, all of Plaintiff's claims fall squarely within the Supreme Court's and Sixth Circuit's holdings and are preempted for the same reasons. Numerous federal district courts in this circuit and elsewhere have reached the same conclusion as to cases involving a variety of claims. *See, e.g.*, *Fulgenzi*, 2012 WL 1110009, at *5 (dismissing common law and statutory product liability claims brought against a generic manufacturer of metoclopramide on preemption grounds); *see also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012) (negligence claims against generic manufacturers preempted and dismissed in multi-jurisdiction MDL); *Brinkley v. Pfizer, Inc.*, No. 10-0274-CV-W-SOW, 2012 WL 1564945 (W.D. Mo. Apr. 12, 2012) (negligence claims against generic manufacturers preempted and dismissed); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, MDL No. 2243, Civ. No. 08-008 (GEB-LHG), 2011

WL 5903623 (D.N.J. Nov. 21, 2011) (negligence claims against generic manufacturers preempted and dismissed); *Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011) (same). *Mensing*'s impact is clear: preemption is dispositive of Plaintiff's lawsuit.

The decision of the U.S. District Court for the Northern District of Ohio in *Fulgenzi v. PLIVA* is particularly applicable here. In *Fulgenzi*, the plaintiff brought negligence, breach of warranty and product liability claims against a manufacturer of generic metoclopramide that are in essence indistinguishable from the causes of action in the instant case.[6] The district court found that these product liability claims, as well as additional statutory and common law claims, including fraud, were "at the core, failure-to-warn claims that are clearly preempted by *Mensing*." *Fulgenzi*, 2012 WL 1110009, at *7. The *Fulgenzi* Court stated:

> [A]ll of the claims, including those otherwise abrogated by the OPLA, hinge on the warnings the drug manufacturers gave, or from Plaintiff's perspective, failed to give. Because the essence of these claims is that PLIVA and others marketed and sold a product as safe when they should have advised doctors and patients of the risk created by long-term use of the medication, the case comes down to the warning . . . . As such, the claims in this action are preempted by *Mensing*.

*Id.* at *7 (citations omitted).

As in *Fulgenzi*, all of Mr. Arters' claims at their root are failure-to-warn claims that attack the sufficiency of the warnings that Eon provided in its product labeling:

- "[w]hen Eon placed its Amiodarone in the stream of commerce, Amiodarone was not accompanied by any meaningful warnings regarding the significant risk of medical conditions, including . . . eye damage." (Compl. ¶ 150.)

- Eon "[f]ailed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of Amiodarone, [and]

[6] Although the plaintiff in *Fulgenzi* pled additional common law causes of action, the District Court found that negligence, breach of warranty and product liability under the Ohio Product Liability Act ("OPLA") were the three basic theories of product liability under Ohio law. *Id.* at *5. As such, the court found plaintiff's additional common law product liability claims had been abrogated by the OPLA. *Id* at *6.

> "[f]ailed to advise the US medical profession" of those risks." (*Id.* ¶ 154(a), (d).)
>
> - Eon "placed this drug into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product." (*Id.* ¶ 163.)
>
> - "Had adequate warnings or instructions been provided, the Plaintiff would not have taken the drugs as they did, and would not have suffered harmful side effects, including blindness." (*Id.* ¶ 173.)
>
> - "Defendants had a duty to disclose but intentionally omitted . . . information in its product labeling and/or intentionally failed to disclose fully and adequately the risk of personal injury resulting from Amiodarone to physicians and consumers." (*Id.* ¶ 182.)

These claims are exactly the sort of state failure-to-warn claims *Mensing* and its progeny have held are preempted by federal law. *See, e.g.*, *Mensing*, 131 S. Ct. at 2578; *Smith*, 657 F.3d at 423; *Fulgenzi* at *5.

Nor may Plaintiff circumvent preemption by arguing that Eon should have strengthened its warnings through letters to physicians, or any of the other independent label change options arguably available to brand manufacturers. *Mensing*, 131 S. Ct. at 2575-76. Even if Plaintiff seeks now to assert some other duty to strengthen the warnings provided with amiodarone, such as a Dear Doctor Letter or other communication to physicians or patients, *Mensing* makes clear these were not legally viable options, because all communications to physicians or the public about potential drug risks are considered labeling and must be consistent with the brand manufacturer's labeling. *Id.* at 2576 (if generic drug manufacturers were to provide warning information directly to doctors that the brand manufacturer did not communicate to doctors in identical fashion, it "would inaccurately imply a therapeutic difference between the brand and generic drugs"); *see also* 21 C.F.R. § 202.1(l)(2) (expansively defining drug labeling to include, *inter alia*, brochures, mailings, letters, and literature). For these reasons, dozens of federal courts

have found that allegations of fraud, misrepresentation, and concealment ultimately depend upon an alleged failure to adequately warn about a drug's risks, and thus are all preempted. *See, e.g. Fulgenzi* at *7 (claims attacking the representations or disclosures generic manufacturers should have made to patients and doctors "come[] down to the warning," and are preempted).

The only way a generic manufacturer could conceivably bring about a labeling change would be to attempt to persuade the FDA and the brand name manufacturer that a labeling change was warranted. *Id.* at 2578. However, any decision to change the labeling would be made by the FDA in consultation with the brand manufacturer only. *Id.* Thus, the Supreme Court ruled, a generic manufacturer could not possibly comply with state tort law claims while complying with federal labeling requirements law. *Id.* at 2578-81. Because of this conflict, Plaintiff's state tort law claims attacking the sufficiency of Eon's warnings are preempted. *Id.*

## CONCLUSION

It was impossible as a matter of law for Eon to comply with both federal drug labeling requirements and the state tort law duties Plaintiff seeks to enforce in this case. State law claims that impermissibly conflict with federal law must give way. Each of Plaintiff's claims seeks to impose conflicting state law requirements upon Eon, and federal law in this instance must prevail. For the foregoing reasons, Defendants respectfully requests that this Court dismiss Plaintiff's Complaint in its entirety, and grant such other and further relief as the Court deems appropriate.

Respectfully submitted,

*s/ David W. Walulik*

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**IN THE UNITED STATES DISTRICT COURT**
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| FREDERICK ARTERS, | ) |
| | ) |
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| | ) |
| SANDOZ INC., FORMERLY KNOWN AS GENEVA PHARMACEUTICALS, INC., | ) |
| | ) |
| AND | ) |
| | ) |
| EON LABS, INC., FORMERLY KNOWN AS EON LABS MANUFACTURING, INC. | ) |
| | ) |
| Defendants. | ) |

**CERTIFICATE OF SERVICE**

This is to certify that on October 19, 2012, a true and correct copy of the foregoing was served upon the following counsel electronically via the Court's ECF system and also by US Mail:

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Dated: October 19, 2012
DC:50962709.1

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